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TECHNICAL NOTE

Off-licence Use of the Angio-Seal™ Arterial Puncture Closure Device

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Introduction

Arterial puncture for interventional radiological procedures is associated with infrequent but significant complications.[1,2] The Angio-Seal™ device is designed to provide rapid and secure haemostasis after arterial puncture and is currently licensed for use in femoral arterial puncture sites where it has been demonstrated to be both safe and effective.[3,4] However, many angiographic procedures are performed by puncture of other sites and vessels (autologous and synthetic grafts, arterio-venous fistulas) and reducing complications in these groups of patients is probably more important since they are more likely to have significant co-morbidities and any complication is potentially more serious. We describe the off-license use of the Angio-Seal™ device in 12 patients with no complications.

Patients and Methods

Patients were identified from the audit records of the Leicester General Hospital radiology department. This department provides interventional vascular radiology services for vascular surgery, general surgery, nephrology and renal transplantation. No cardiac angiography is performed. A retrospective case note review was performed of all patients who had an Angio-Seal™ device inserted between 25/5/2001 (when the device was first used in our Hospital) and 26/7/2001. Case-notes were retrieved and those found to be concerning procedures where the Angio-Seal™ device was used off-licence were reviewed by one of the authors (MJB).

Results

Out of a total of 86 occasions where the Angio-Seal™ was used during the study period, in 12 cases this was in situations other than those described as indications in the product literature (Table 1). It was used on six occasions in arterio-venous haemodialysis fistulas (3 brachio-cephalic, 1 brachio-axilliary, and 2 femoro-femoral PTFE grafts) and 3 times in vascular bypass grafts (2 autologous vein, 1 PTFE graft).

In one case the Angio-Seal™ was placed into the femoral vein. This was in a patient with the rare condition of afibrinogenaemia. One week prior to the episode where the Angio-Seal™ was used the patient had developed a significant neck haematoma requiring surgical evacuation after a venous catheter in the left internal jugular vein had been removed. Venous

Table 1. Sites of "Off-licence" Angio-Seal™ deployment.

Site Angio-Seal™ deployed	*n*
Arterio-venous haemodialysis fistula	6
(PTFE graft)	(2)
Peripheral arterial bypass grafts	3
(PTFE graft)	(1)
Femoral artery after failure of haemostasis by manual compression	2
Femoral vein	1

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access had been maintained by the placement of a femoral venous catheter. In order to prevent similar complications when the femoral venous catheter was removed, it was exchanged over a guidewire for an Angio-Seal™ with no complications.

Two patients who had undergone diagnostic lower-limb angiography via a femoral artery puncture developed significant bleeding following their procedure despite adequate manual pressure. In these two patients the original arterial puncture was located using the Angio-Seal™ dilator, re-cannulated and an Angio-Seal™ placed with immediate haemostasis achieved in both cases.

None of the above patients developed haematoma, bleeding or distal arterial complications after the insertion of the Angio-Seal™ device.

Discussion

This study demonstrates the versatility of the Angio-Seal™ device in situations for which it was not specifically designed, such as deployment in veins and vascular grafts (autologous vein or synthetic). Use in these situations may enable the treatment of patients who otherwise would have been denied treatment due to the high risk of puncture site complications.

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